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Gl&Hepatology News

July 2020



American

Association

Gastroenterological

Dr. Shahnaz Sultan, AGAF, lead author and chair, AGA Clinical Guideline Committee, produced recommendations for use of personal protective equipment by physicians and nurses performing GI procedures.

COVID-19 guideline update

Wear N95 masks during endoscopy

BY RICHARD MARK KIRKNER MDedge News

ausea, vomiting, and diarrhea are gastrointestinal symptoms that COVID-19 patients have had, and up to 30% have been reported to have liver symptoms. Because patients with these symptoms may require endoscopy, the American Gastroenterological Association has issued a rapid recommendation document that advises physicians and health care workers to use N95 masks, double gloves, and negative-pressure rooms when performing GI procedures during the COVID-19 pandemic.

The recommendations, published in Gastroenterology (2020. doi: 10.1053/j. gastro.2020.03.072), also cover non-COVID-19 patients and situations where N95 masks should be used, offer guidelines for triaging patients for endoscopy and timing of nonurgent procedures, and evaluate the latest evidence in the incidence of GI and liver manifestations of COVID-19. The *See* **N95 masks** · page 20

American Cancer Society update

'It is best not to drink alcohol'

BY ROXANNE NELSON, RN, BSN

n its updated cancer prevention guidelines, the American Cancer Society now recommends that "it is best not to drink alcohol."

Previously, ACS suggested that, for those who consume alcoholic beverages, intake should be no more than one drink per day for women or two per day for men. That recommendation is still in place, but is now accompanied by this new, stronger directive.

The revised guidelines also place more emphasis on reducing the consumption of processed and red meat and highly processed foods, and on increasing physical activity.

But importantly, there is

also a call for action from public, private, and community organizations to work together to increase access to affordable, nutritious foods and physical activity.

"Making healthy choices can be challenging for many, and there are strategies included in the guidelines that communities can undertake to help reduce barriers to eating well and physical activity," said Laura Makaroff, DO, American Cancer Society senior vice president.

The guidelines were published in CA: A Cancer Journal for Clinicians.

The link between cancer and lifestyle factors has long been established, and for the past 4 decades, both government and lead-See **Cancer** • page 17

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IBD: Steroids, but not TNF blockers, raise risk of severe COVID-19

BY WILL PASS MDedge News

or patients with inflammatory bowel disease (IBD) who develop coronavirus disease of 2019, corticosteroid use may significantly increase risk of severe disease, according to data from more than 500 patients.

Use of sulfasalazine or 5-aminosalicylates (5-ASAs) also increased risk of severe COVID-19, albeit to a lesser degree, reported co-lead authors Erica J. Brenner, MD, of University of North Carolina Children's Hospital, Chapel

See Steroids · page 18



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LETTER FROM THE BOARD OF EDITORS *Call to action (again)*

his editorial is the first to be published in *GI & Hepatology News* since the murder of George Floyd in Minneapolis. The corner of 38th and Chicago is 9 miles from my home in Bloomington, Minn. This corner became the epicenter of protests that have spread around the nation and world. Early on, protests were accompanied by widespread riots, looting, and destruction. In the ensuing weeks, this corner has become a memorial for Mr. Floyd and a place where people now go to reflect, pray, pay tribute, and pledge to work for change.

A coalition of willing businesses has formed in the area around 38th and Chicago. The largest employer in the area is Allina Health (I sit on the Governing Board of Allina Health). Our flagship hospital is 8 blocks from the site of George Floyd's memorial. We will be a change leader by committing funds for local rebuilding, ensuring use of construction firms that promote minority workers (as was done when the Viking's stadium was built), examining our investment portfolio with racial equity as one guiding principle, increasing our focus on barriers to access, enhancing equity education of our workforce, and working with city and state leaders to promote police reform.

As the Editor in Chief of the official newspaper of the AGA, I invited our board of editors to stand united in our condemnation of the racial injustices that led to the protests we now see. We each agree with the message from the combined Governing Boards of our GI societies (published June 5, 2020) stating "As health care providers, we have dedicated our lives to caring for our fellow human beings. Therefore, we are compelled to speak out against any treatment that results in unacceptable disparities that marginalize the vulnerable among us."

Our responsibility as editors is to guide the content we deliver, ensuring its relevancy to our readers. In this light, we commit to delivering content that highlights racial injustices and health disparities for all people, as we seek to understand the many factors that result in barriers to health. We will emphasize content that leads to impactful change and will highlight progress we make as a specialty. We hope our collective work will help ensure that George Floyd's memory, and the memories of all such victims, become a catalyst for permanent cultural change.

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Top AGA Community patient cases

hysicians with difficult patient scenarios regularly bring their questions to the AGA Community

(https://community.gastro.org) to seek advice from colleagues about therapy and disease management

options, best practices, and diagnoses. The upgraded networking platform now features a newsfeed for difficult patient scenarios and regularly scheduled Round-



table discussions with experts in the field.

In case you missed it, here are some clinical discussions and Roundtables in the newsfeed this month:

- The future of telemedicine payments (https://community.gastro.org/posts/21604).
- The AGA Diversity Committee's message on racism and leading change (https://community.gastro.org/ posts/21513).
- Resuming endoscopy in low COVID prevalence areas (https://community.gastro.org/posts/21430).
- Early liver transplantation for alcoholic hepatitis (https://community.gastro.org/posts/21391).
- GERD phenotypes: Review in AGA *Clinical Gastroenterology & Hepatology* (https://community.gastro. org/posts/21386).

Roundtables:

- GI COVID-19 connection: Viral impacts on the microbiome (https://community.gastro.org/discussions).
- Q&A with guideline authors: Probiotics in the management of gastrointestinal diseases (https:// community.gastro.org/discussions).

View all upcoming Roundtables in the community at https://community.gastro.org/discussions.

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Electrosurgical choices lead to similar results

BY WILL PASS MDedge News

or endoscopists performing electrosurgical snare resection of large colorectal polyps, choosing between the blue foot pedal and the yellow foot pedal may be the least important step of the day, according to data from almost 1,000 patients.

Risks of severe adverse events and polyp recurrence were similar between cases in which blended current (yellow pedal) was used and those in which coagulation current (blue pedal) was used, reported lead author Heiko Pohl, MD, of Geisel School of Medicine at Dartmouth, Hanover, N.H., and colleagues.

"Although electrosurgical application is a fundamental aspect of polypectomy, various currents and settings are clinically used, and there are no accepted standards of practice," the investigators wrote in Gastroenterology.

According to Dr. Pohl and colleagues, a 2004 study showed that the split between endoscopists using coagulation current and those using blended current was about 50-50 (46% vs. 46%), but no studies to date have tested the relative safety or efficacy of these approaches.

The investigators aimed to address this knowledge gap with a single-blinded study involving 928 patients who underwent endoscopic mucosal resection of nonpedunculated, large (20 mm or larger) colorectal polyps with an Erbe Vio® 300D electrosurgical unit (Erbe USA, Marietta, Ga.) at 18 medical centers.

Patients were randomized in 2x2 factorial design involving clip closure versus no clip closure, and blended current (Endocut Q) versus pure coagulation current (Forced Coagulation). Although electrosurgical setting was initially a secondary intervention in the trial, post hoc analysis showed that interaction between the interventions was not significant (P = .957), allowing for the present, independent analysis of current type.

For this analysis, the primary outcome was severe adverse event rate, both during the procedure, and after the procedure for up to 30 days. Secondary outcomes included proportion of polyps completely excised and recurrence rate at time of first surveillance endoscopy.

Out of 928 patients randomized, 919 completed 30-day follow-up,

and 675 underwent first surveillance colonoscopy. Baseline characteristics were similar between groups, apart from the proportion of individuals with more than one large polyp, which was significantly greater in the Endocut O group (8.6% vs. 4.5%; *P* = .012), although

'Overall, polyp resection with Endocut or Forced **Coagulation did not differ with** respect to severe adverse events, complete resection rate, or polyp recurrence.

the investigators noted that this imbalance did not affect main outcomes.

Rates of severe adverse events were similar between groups: 7.2% for the Endocut Q group and 7.9% for the Forced Coagulation group (P = .762). Groups also had similar rates of intra- and postprocedure adverse events, and types of adverse events.

Efficacy measures also revealed high similarity between cutting techniques. Endoscopists using

Endocut achieved complete polyp removal 96% of the time, compared with 95% of the time when using Forced Coagulation (P = .267). Piecemeal resection rates were similar, at 90% and 87% for Endocut Q and Forced Coagulation, respectively (P = .270).

Although Endocut Q less frequently resulted in small residual tissue islands after initial snare resection (35% vs. 41%; *P* = .041), it more often caused intraprocedural bleeding that required treatment (17% vs. 11%; P = .006).

According to Dr. Pohl and colleagues, previous discussions have included concerns that such bleeding may impair visualization and therefore lead to higher rates of polyp recurrence; but surveillance colonoscopy, which was performed in 79% of patients, revealed a polyp recurrence rate of 17% for each group.

"Although we did not find a difference in recurrence between the two groups, our study cannot completely exclude this possibility," the investigators added.

They also noted that six perforations occurred in the Endocut Q group, compared with three in the Forced Coagulation group, and suggested that this risk may be real, yet statistically unsupported by the present analysis because of sample size.

"Endoscopists using Endocut should therefore be aware of this potential risk and [ensure] that no muscularis propria is entrapped in the snare before electrosurgery is applied," the investigators wrote.

Still, the investigators' final conclusion supported the existing method of decision-making: personal choice.

"Overall, polyp resection with Endocut or Forced Coagulation did not differ with respect to severe adverse events, complete resection rate, or polyp recurrence," they wrote. "This study therefore supports an individual approach based on endoscopist preference."

The study was funded by Boston Scientific and the American College of Gastroenterology. The investigators disclosed additional relationships with Medtronic, Olympus, Cook Endoscopy, and others.

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SOURCE: Pohl H et al. Gastroenterology. 2020 Mar 12. doi: 10.1053/j.gastro.2020.03.014.

here has long been a debate over which type of electrosurgical setting is best for colon polyp resection. Endoscopists can use either a blended current (yellow pedal) or a coagulation current (blue

pedal). The choice is based on the endoscopists' preference. However, few data have been available to support one setting versus the other.

This study by Pohl et al. pursued the burning question of yellow or blue pedal? This single-blind randomized multicenter trial compared the two commonly used electrosurgical settings (Blended Current/ Endocut Q vs. Forced Coagulation) for the resection of large colorectal polyps and found no difference in the risk of serious adverse events, complete resection rate, or polyp recurrence, thus supporting the current practice that electrosurgical settings can be selected based on endoscopist expertise and preference.

A few important highlights from this well-designed study are worth mentioning. Although there was no significant difference in perforation, it should be noted that fewer patients had a perforation event in the Forced Coagulation group than in the Endocut Q group (3 vs. 6 patients; P = .320). In addition, the study demonstrated that the rate of polyp recurrence did not differ significantly between the two groups (17.4% vs. 16.5%; *P* = .762). while the rate of macroscopically visible recurrence was not statistically different, a histologic recurrence without visible polyp

tissue was found slightly less frequent in the Forced Coagulation group than in the Endocut Q group (3.1% vs. 6.0%; *P* = .07).

Finally, another important observation, intraprocedural bleeding requiring treatment,

occurred less frequently during resection with Forced Coagulation than with Endocut Q (11% vs. 17%, *P* = .006); however, this difference did not affect overall safety and efficacy. This is an important finding since bleeding can affect the field of view during polypectomy, which can potentially increase the risk of other serious adverse events such as perforation or increase the risk of recurrence because the endoscopist may not completely resect the polyp

Dr. Gress

This study provides important insights into the potential risks associated with blended vs. coagulation currents. It further shows there is no difference in safety and efficacy of polypectomy using either a blended current or coagulation current, thus supporting current practice. However, the authors make it clear that a larger study will be needed to better answer such questions as polyp recurrence and perforation more definitively.

Frank G. Gress, MD, MBA, AGAF, is senior faculty at the Icahn School of Medicine at Mount Sinai, New York; chief, division of gastroenterology and hepatology, and director of the Center for Interventional Endoscopy at Mount Sinai Hospital South Nassau. He has no conflicts.

FibroScan: M probe underestimates hepatic fat content

BY WILL PASS MDedge News

hen performing transient elastography (FibroScan) to evaluate patients for hepatic steatosis, using an M probe instead of an XL probe may significantly underestimate hepatic fat content, according to investigators.

The findings, which were independent of body weight, suggest that probe-specific controlled attenuation parameter (CAP) thresholds are needed to accurately interpret FibroScan results, reported lead author Cyrielle Caussy, MD, PhD, of the University of California, San Diego, and colleagues.

"We have previously determined the optimal threshold of CAP using either [an] M or XL probe for the detection of ... nonalcoholic fatty liver disease (NAFLD)," the investigators wrote in Clinical Gastroenterology and Hepatology. "However, head-to-head comparison of consecutive measurements of CAP with both the M and XL probes versus MRI-PDFF [proton density fat fraction] ... has not been reported yet."

Dr. Caussy and colleagues set out to do just that. They enrolled 105 individuals with and without NAFLD who had a mean body mass index of 30.6 kg/m², as this represented a typical population screened for NAFLD. After evaluation for other causes of hepatic steatosis and liver disease, participants underwent MRI-PDFF, which served as a gold standard, followed by FibroScan using both M and XL probes on the same day.

The primary outcome was hepatic steatosis (MRI-PDFF of at least 5%), while the secondary outcome was MRI-PDFF-detected hepatic fat

content of at least 10%, the latter of which has been "used in several therapeutic trials as inclusion criteria," the investigators noted.

A total of 100 participants were included in the final analysis, of whom two-thirds (66%) underwent MRI and FibroScan on the same day, with a mean interval between test types of 11 days. Most participants (68%) had an MRI-PDFF of at least 5%, while almost half (48%) exceeded an MRI-PDFF of 10%.

Individuals screened with an M probe who have a CAP of 294 dB/m or more should be considered positive for NAFLD, while those screened with an XL probe need to have a CAP of at least 307 dB/m to be NAFLD positive.

The mean CAP measurement with the M probe was 310 dB/m, which was significantly lower than the mean value detected by the XL probe, which was 317 dB/m (P = .007). In participants with hepatic steatosis, when the M probe was used for those with a BMI of less than 30, and the XL probe was used for those with a BMI of 30 or more, the M probe still provided a significantly lower measure of hepatic fat content (312 vs. 345 dB/m; P = .0035).

"[T]hese results have direct application in routine clinical practice," the investigators wrote, "as [they] will help clinicians interpreting CAP measurements depending on the type of probe used."

Dr. Caussy and colleagues went on to offer a diagnostic algorithm involving optimal probe-specific thresholds for CAP based on hepatic fat content. Individuals screened with an M probe who have a CAP of 294 dB/m or more should be considered positive for NAFLD, while patients screened with an XL probe need to have a CAP of at least 307 dB/m to be NAFLD positive.

For the XL probe, but not the M probe, diagnostic accuracy depended upon an interquartile range of less than 30 dB/m. The investigators noted that this finding should alter the interpretation of a 2019 study by Eddowes and colleagues, which concluded that interquartile range was unrelated to diagnostic accuracy.

"As Eddowes et al. did not perform head-tohead comparison of CAP measurement with both the M and XL probes, this important difference could not have been observed," the investigators wrote, noting that "an interquartile range of CAP below 30 dB/m should be considered as a quality indicator that significantly improves the diagnostic performance of CAP using the XL probe for the detection of hepatic steatosis in NAFLD."

The investigators concluded by suggesting that their findings will drive research forward.

"The use of these new thresholds will help to further assess the clinical utility of CAP for the detection of hepatic steatosis and its cost-effectiveness, compared with other modalities, to develop optimal strategies for the screening of NAFLD," they wrote.

The study was funded by Atlantic Philanthropies, the John A. Hartford Foundation, the American Gastroenterological Association, and others. The investigators disclosed no conflicts of interest.

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SOURCE: Caussy C et al. Clin Gastro Hepatol. 2019 Dec 13. doi: 10.1016/j.cgh.2019.11.060.

Organoid model unveils intestinal response to Shiga toxin

BY WILL PASS MDedge News

E a complex intestinal response involving transcriptional changes, necrosis, apoptotic cell death, cellular proliferation, and cross-talk between epithelial and mesenchymal cells, according to investigators.

The study explored new territory in Shiga toxin research, enabled by the use of human intestinal organoids (HIOs), reported lead author Suman Pradhan, PhD, of the University of Cincinnati, and colleagues.

Each year, Shiga toxin–producing *Escherichia coli* infections cause approximately 3 million cases of bloody diarrheal disease, with about 4,000 of those patients developing the life-threatening complication of hemolytic uremic syndrome (HUS), the investigators wrote in

Cellular and Molecular Gastroenterology and Hepatology.

But little is known about the underlying biological processes driving Shiga-induced disease.

"Developing effective interventions for disease resulting from Shiga toxin is exacerbated by a lack of tractable model systems," the investigators wrote. "Mice do not develop the symptoms characteristic of HUS, and the murine intestinal tract is resistant to Shiga toxin."

To overcome this obstacle, Dr. Pradhan and colleagues turned to HIOs, which are grown in culture by directing differentiation of pluripotent stem cells. HIOs represent the small bowel, complete with a lumen surrounded by epithelial and mesenchymal layers that include typical cell types, such as goblet cells and myofibroblasts. The model is made more realistic by transplantation into mice, where it grows under the kidney capsule to form crypts, structured villi, and proliferating progenitor zones. And HIOs grown with neuronal precursors develop an enteric nervous system, com-

'[Shiga toxin] was transferred from the apical to the basolateral surface in the absence of loss of epithelial barrier function'; this finding explains how Shiga toxin can quickly access the circulatory system.

plete with functional peristalsis.

For the present study, the investigators evaluated the effect of Shiga toxin on HIOs both in culture and after transplantation into mice.

First, they demonstrated that HIOs in culture expressed glycolipid Gb3, the Shiga toxin receptor. "Reports regarding expression of glycolipid Gb3 ... on human intestine have been inconsistent," the investigators noted. "For negative reports, the inability to detect Gb3 could be owing to technical limitations."

Next, Dr. Pradhan and colleagues showed that HIOs were susceptible to Shiga toxin whether it be delivered lumenally or basolaterally, which respectively represent intestinal exposure and exposure via circulating toxin or after breakdown of the epithelial barrier. Leakage from the lumen was observed with both Shiga toxin 1 (Stx1) and 2 (Stx2). Subsequent testing involved only Stx2, as this form is more relevant to human disease.

In addition to lumenal leakage, Stx2 exposure caused significant transcriptional up-regulation of multiple gene families, including those involved in cellular transport *Continued on following page*

Meta-analysis: For large proximal colorectal polyps, clipping prevents bleeding

BY WILL PASS MDedge News

rophylactically clipping large proximal colorectal lesions after resection may reduce risk of postprocedural bleeding, according to a meta-analysis involving nine randomized controlled trials.

Across all lesions, prophylactic clipping had no significant benefit, but when considering only large proximal lesions, clipping reduced bleeding risk by 63%, reported lead author Marco Spadaccini, MD, of Humanitas University, Rozzano, Italy, and colleagues.

"Despite lack of high-quality evidence, prophylactic clipping has been advocated as a technique to reduce the risk of postprocedural bleeding," the investigators wrote in Gastroenterology, referring to the European Society of Gastrointestinal Endoscopy recommendation that is based on patient risk factors.

Although previous meta-analyses reported that prophylactic clipping had no protective effect, these studies were "at high risk of bias" and predominantly evaluated lesions less than 20 mm in diameter, the investigators wrote.

Dr. Spadaccini and colleagues suggested that data from more recent, high-quality, randomized controlled trials could be used to identify subgroups that may benefit from clipping. This knowledge is particularly valuable considering the "costs and technical complexity" involved in the procedure, they noted.

The present meta-analysis comprised nine trials that included 7,197 colorectal lesions, of which 49.2% were proximally located and 22.5% were large (at least 20 mm in diameter).

Across all lesions, postprocedural bleeding occurred in 2.2% of clipped lesions and 3.3% of nonclipped lesions, a difference that was not statistically significant (P = .072). But for lesions 20 mm or larger, clipping was associated with a significantly lower rate of bleeding (4.3% vs. 7.6%; relative risk, 0.51; 95% confidence interval, 0.33-0.78; P = .020). Similarly, clipping in the proximal location was independently associated with reduced bleeding risk (3.0% vs. 6.2%; RR, 0.53; 95% CI, 0.35-0.81; P less than .001). A multilevel meta-regression added further clarity by combining both size and location; it showed that clipping had a significant protective effect for large proximal lesions (RR, 0.37; 95% CI, 0.22-0.61; *P* = .021), but not for those that were small and proximal (RR, 0.88; 95% CI, 0.48-1.62; *P* = .581).

"According to our meta-analysis, routine practice of endoscopic clipping as a prophylactic intervention does not reduce the risk of postpolypectomy bleeding," the investigators wrote. "However, clipping was effective in reducing the risk of postprocedural bleeding by nearly 50% for large lesions. If such lesions do not undergo endoscopic clipping, there was fourfold increase in the baseline risk of post-procedural bleeding as compared with those less than 20 mm."

While the present analysis suggested that clipping was beneficial only for large lesions in the proximal colon, the investigators noted that the protective effect of clipping large lesions in the distal colon (RR, 0.70; 95% CI, 0.22-2.27) was "somewhat intermediate ... albeit not statistically significant" and driven by data from one trial.

Perhaps the most promising aspects of this study

ability to study Stx in in vitro cultures that encom-

tions and cell-cell interactions pertinent to disease.

Thus, while the clinical relevance of in

vivo modeling with transplanted human

intestinal organoids needs further clar-

ification, critical questions can now be

explored such as: During STEC infection,

which are the important mucosal cell-cell

interactions? Do immature IECs express

the Stx receptor and respond differently than mature IECs? And how do we block

Stx movement across IECs and prevent its

access to circulation? These questions can

pass much of the complex developmental transi-

and model system center on the demonstrated

Continued on following page

Continued from previous page

and metabolic processes. Increased expression also was observed for epithelial structural proteins, lineage-specific proteins, factors involved in mucus layer formation and stabilization, and cytokines interleukin-18 and CCL15.

In both epithelial and mesenchymal layers, transcriptional changes were accompanied by cellular necrosis and apoptosis, and, to a greater degree with interstitial exposure, cellular proliferation.

With lumenal exposure, mesenchymal necrosis was observed before loss of epithelial barrier function, indicating toxin access to mesenchymal cells. This phenomenon was explained by transcytosis, which the investigators observed in two-dimensional monolayers of enteroids grown in Transwells.

'[Shiga toxin] was transferred from the apical to the basolateral surface in the absence of loss of epithelial barrier function," the investigators wrote, noting that this finding explains how Shiga toxin can quickly access the circulatory system, and from there damage the kidneys and brain, as seen in cases of HUS.

Mice with transplanted HIOs, and those receiving HIOs with an enteric nervous system (HIO + ENS), lost weight when organoids were injected with 10 ng of Stx2. Mice with HIO + ENS transplants developed more

imited therapies exist to mitigate the life-threatening sequelae of Shiga toxin (Stx)-producing Escherichia coli (STEC) infections. Stx continues to be a leading cause of hemolytic uremic syndrome and can devastate the kidneys, central nervous system,

and other vital organs. Conflicting results from animal models and cell lines have left important questions unanswered, slowing therapy development. This study by Pradhan et al. takes advantage of the human intestinal organoid system to provide insight to questions pertinent to understanding Stx mechanism of action. Importantly, the authors find that intestinal epithelial cells (IECs) are a direct target of Stx and express the Stx receptor, Gb3, a point that had not been previously well established. They fur-

ther confirm that IECs efficiently transport Stx from the apical to basolateral surface, before barrier integrity is compromised. This likely allows Stx to rapidly access circulation and other affected organs to cause disease.

Dr. Belle

Nicole Maloney Belle, MD, PhD, is an instructor of medicine, division of gastroenterology and hepatology, at the University of Pennsylvania, Philadelphia. She has no conflicts.

all be addressed.

severe responses, prompting closer analysis.

Postmortem histologic examination of HIO + ENS transplants revealed epithelial damage and blood accumulation in the mesenchyme and villi. Additional staining showed signs of apoptosis and mesenchymal-epithelial transition.

Dr. Pradham and colleagues suggested that their findings could inform therapeutic research.

"If preventing cellular death is

to be an effective intervention, it is likely that both necrosis and apoptosis need to be targeted," the investigators wrote.

More generally, the study supports the use of HIOs as a disease model for future investigations.

"The advent of stem cell-derived human tissue models, both in vitro and in vivo, has a tremendous potential to increase our understanding of Shiga toxin disease and lead to development of therapeutic interven-

tions," the investigators concluded. The study was funded by the National Institutes of Health, the Center for Clinical and Translational Science, the National Institute of Diabetes and Digestive and Kidney Diseases, and others. The investigators disclosed no conflicts of interest. ginews@gastro.org

SOURCE: Pradhan S et al. Cell Mol Gastroenterol Hepatol. 2020 Mar 5. doi: 10.1016/j.jcmgh.2020.02.006.



CLINICAL CHALLENGES AND IMAGES

What is your diagnosis?

By Amrit K. Kamboj, MD, Vandana Nehra, MD, and Cadman L. Leggett, MD. Published previously in Gastroenterology (2019;156[8]:2144-5).

A 70-year-old woman with a past medical history of gastroesophageal reflux disease presented for evaluation of difficulty swallowing. She described trouble with solid food bolus transition, but denied difficulty swallowing liquids or episodes of choking. Concurrently, she reported progressive symptoms of retrosternal burning and epigastric pain despite adhering to twice-daily proton pump inhibitor therapy. Her physical examination re-

vealed a soft abdomen with mild

tenderness to deep palpation over the epigastrium. Laboratory studies showed no evidence of anemia or leukocytosis. She underwent a video-swallow study that demonstrated a normal swallowing mechanism without evidence of pooling of contrast or aspiration. An esophagogastroduodenoscopy was performed that showed a 7-cm hiatal hernia without evidence of erosive esophagitis or stenosis at the gastroesophageal junction. Upon careful withdrawal, a polypoid lesion was noted in the oropharynx (Figure A). Neck computed tomography scans revealed a 13-mm, well-circumscribed, round mass in the right piriform sinus (Figure B). What is the lesion responsible for this patient's oropharyngeal dysphagia?

The diagnosis is on page 16.

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Continued from previous page

"[T]his was not confirmed by other studies generating some uncertainty on the benefit of prophylactic clipping for large distal lesions," the investigators wrote. "Thus, the decision for large and distal lesions should be tailored, especially taking into consideration other patient- and polyp-risk factors for postprocedural bleeding, such as the use of anti-thrombotic agents or intraprocedural bleeding."

In contrast, the findings indicated that clipping is unnecessary for lesions less than 20 mm, the investigators wrote.

"Considering that clips are expensive and their placement might be technically demanding, prophylactic clipping tailored for a subgroup of higher-risk lesions/patients would decrease in parallel both adverse events and costs," the investigators concluded.

The investigators reported no external funding or conflicts of interest. ginews@gastro.org

SOURCE: Spadaccini M et al. Gastroenterology. 2020 Apr 1. doi: 10.1053/j.gastro.2020.03.051.



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Epstein-Barr virus may worsen immune checkpoint inhibitor-induced colitis

BY WILL PASS MDedge News

or patients with immune checkpoint inhibitor-induced colitis, Epstein-Barr virus (EBV) infection may increase risks of steroid-refractory disease and ulcers that contribute to colonic perforation, according to investigators.

Pending further research, routine monitoring of EBV status may be needed for patients undergoing checkpoint inhibitor therapy, reported lead author Matthew R. Pugh, FRCPath, of University Hospital of Wales, Cardiff, and colleagues.

EBVMCUs 'likely contribute directly to colonic perforation,' since lesions are characterized by a form of localized tissue destruction that has been previously associated with colonic perforation in Crohn's disease.

"Few studies have investigated the role of viruses in the pathogenesis of immune-related colitis," the investigators wrote. Their report is in Clinical Gastroenterology and Hepatology. While cytomegalovirus has been linked with worse disease, no studies to date have evaluated the role of EBV, they noted, despite theoretical concerns.

"A spectrum of EBV-positive lymphoproliferations shows a predilection for the GI tract, ranging from indolent lesions to aggressive lymphomas," the investigators wrote. "One such proliferation, EBV-positive mucocutaneous ulcer (EBVMCU), is an indolent, ulcerating process associated with immunosuppression," they added, referring to studies involving patients with inflammatory bowel disease.

To determine if EBV could be playing a similar role in cancer immunotherapy, the investigators retrospectively analyzed colon tissue samples from 16 patients who developed colitis after undergoing immune checkpoint inhibitor therapy between 2010 and 2018. Thirteen patients received an anti-CTLA-4

agent, three were treated with a PD-1 inhibitor, and four received both types of therapy. Most patients had advanced-stage melanoma (n = 14), while the remaining two patients had prostate and renal carcinoma, respectively. Ten samples were biopsies, whereas four specimens were collected from surgical repair of colon perforation.

EBV status was determined by chromogenic in situ hybridization for EBV-encoded small RNA, with positive samples further characterized by immunohistochemistry for CD3, CD15, CD20, CD30, CD138, MUM1, and PAX5. In addition, all samples were immunostained for cytomegalovirus, and PCR was used to assess B-cell and T-cell clonality.

The median time from induction of therapy to colitis onset was approximately 1 month (32.5 days), with symptoms typically lasting 3 weeks (22.5 days). Macroscopically, 10 patients had ulceration, and 6 displayed signs of hemorrhage.

EBVMCUs were found in four patients, of whom three had received anti-CTLA-4 therapy, one had received both anti-CTLA-4 and anti-PD-1 therapy, and all had undergone colonic resection. One case also tested positive for cytomegalovirus

Immunostaining showed that EB-VMCUs had underlying B-cell and linear plasma cell infiltrates, with "a rim of small T lymphocytes at the base." EBV-encoded small RNA expression was found in both plasma cells and small B cells.

The presence of EBVMCUs was significantly associated with more severe colitis.

All four EBV-positive patients had steroid-refractory colitis, compared with only two (12.5%) of the EBV-negative patients (P = .008), a difference that was echoed by the rate of colonic resection (100% vs. 12.5%; P.008). Furthermore, colon perforation occurred in all EBV-positive patients, versus none of the EBV-negative patients (P = .001).

For three EBV-positive patients, preresection biopsy samples were available, allowing for temporal analysis of EBV-encoded small RNA. Earlier samples had reduced or absent EBV-positive lymphoid cells, which offered some etiologic insight.

"The apparent absence or paucity

mmune checkpoint regulators (iCRs) have become common in the treatment for various cancers. Immune-related colitis (irColitis) is among the most common side effects of iCRs, as well as one of

the most common etiologies of fatal toxicities from iCRs. However, much is still unknown on the pathophysiology behind irColitis or its complications.

Pugh et al. performed detailed analyses of the potential role of Epstein-Barr virus (EBV) in irColitis. Rather than depend on serologies for EBV, the investigators utilized robust evaluation for colonic mucosal EBV with in situ hybridization, immunohistochemistry, and polymerase chain reaction. Interestingly, in the EBV-positive patients with endoscopic biopsies performed prior to perforation, EBV RNA were minimal or absent on endoscopic biopsies. This finding suggests EBV may be related to the immunosuppression used to treat the colitis rather than the primary driver of irColitis.

This observation could have important clinical implications in using steroids for irColitis; we may be increasing the risk of per-

of EBV-positive lymphoid cells in biopsies taken before resection suggests that EBVMCU is arising within preexisting immune-mediated inflammation rather than EBV driving the initial inflammatory insult," the investigators wrote.

They suggested that EBVMCUs "likely contribute directly to colonic perforation," since lesions are characterized by a form of localized tissue destruction that has been previously associated with colonic perforation in Crohn's disease and intestinal perforation in rheumatoid arthritis.

Still, mechanisms of action remain unknown. "It is unclear why EBVMCUs should arise in the context of immune checkpoint regulator therapy, which, in contrast to conventional immunosuppressants, results in immune activation," the investigators wrote. "It is possible

foration related to EBV by using steroids or other immunosuppression. While we need to interpret these findings with caution given the small sample size and comparisons between endoscopic



biopsies and surgical specimens for EBV, this study highlights the potential role of EBV in steroid-refractory irColitis. An additional clinical implication from this study is that endoscopic biopsies did not identify patients who would eventually develop colonic perforation. We therefore cannot

assume a patient with negative colonic biopsies for EBV is truly negative. Better means for assessing EBV status and predicting complications are still needed.

Jason K. Hou, MD, AGAF, is assistant professor of medicine and gastroenterology; director of the GI and hepatology fellowship program; and director of research and IBD at Baylor College of Medicine, Houston. He is a staff physician in the department of gastroenterology, and medical director, IBD, at Michael E. DeBakey VA Medical Center, Houston. He has no conflicts of interest.

that these patients may harbor residual immunosuppression resulting from their disease burden, advanced age, and prior immunosuppression."

While more work is needed, Dr. Pugh and colleagues suggested that EBV testing may be valuable for some patients.

"The findings support the need for further studies investigating the role of EBV monitoring in immune checkpoint regulator therapy, which is not currently part of routine protocols."

The study was funded by All Wales Lymphoma Panel. The investigators disclosed no conflicts of interest.

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SOURCE: Pugh MR et al. Clin Gastroenterol Hepatol. 2019 Oct 11. doi: 10.1016/j. cgh.2019.09.031.

A message from new president, Bishr Omary

Dear colleagues,

have the privilege and honor to serve as AGA president as of June 1, 2020. When we look back at the first half of 2020, we will remember the COVID-19 pandemic and the unimaginable loss of life, morbidity, and economic impact it had. We will also remember the grief and anger that have characterized the recent weeks. I hope that the second half of 2020 will be a time that reshapes us for the better and allows us to seize the opportunity to make meaningful changes, in addition to recovering from the impact of the pandemic. The ongoing protests for the past 16 days against police brutality finally have our country recognizing front-andcenter injustices facing African Americans.

While recognition of an injustice is a start, it is essentially meaningless unless action is taken to ensure equity in all facets of society. Of particular interest to AGA is access to health care without bias, addressing racial disparities in health care, diversity within the practice of GI, and supporting the careers of diverse researchers. AGA has a diversity policy and a solid history of programs supporting minority physicians and researchers. We know that's not enough and AGA, with our dedicated committees, staff, and leadership, will continue to implement and assess plans for meaningful improvements. Watch for more on this topic in the future.

In addition, AGA took a pledge with our GI

sister organizations to "continue to advocate for diversity in our staff and governance, grant awards to research health care disparities, en-

> sure quality care for all, and work tirelessly to reduce inequalities in health care delivery and access." We plan to honor this pledge with our own efforts and by making a concerted effort to work with AASLD, ACG, ASGE, DHPA, and other societies, colleagues, and friends. The COVID-19 pandemic

Dr. Omary

has been a major challenge for our practices and to our research community. To all AGA members, please know that we have your back with a stream of practice guidance, business support, advocacy, and funding. You can find these resources collected at www.gastro. org/COVID.

My special thanks to the following AGA members, among several AGA staff and expert participants, for making these resources possible and highly engaging:

- Maria Abreu, who oversees our weekly COVID Connection webinar.
- Shahnaz Sultan and Joseph Lim whose Guidelines and Clinical Practice Update committees have generated evidence-based practice guidance at an incredible pace.
- Vivek Kaul and Vijay Shah who lead regular

townhall webinars with division chiefs to share how GI divisions are pivoting to address the numerous current challenges.

• Rhonda Souza, chair of AGA Council, which is already thinking about how to make DDW 2021 a success.

Throughout my time as AGA president, I plan to communicate with you on a regular basis and welcome your input and suggestions. Watch the AGA Community for updates and announcements. Every other month, I plan to host a Townhall with the AGA President webinar on Zoom, where we can gather to hear from AGA leaders and staff on their work. My first webinar is planned for July 10, 2020, at 11 a.m. United States Eastern time. Watch for more info to come.

My goals are to build on what past president Hashem El-Serag has initiated and to work closely with John Inadomi (president-elect), John Carethers (vice president), the AGA Governing Board, committees, and staff. Along these lines, we will work tirelessly to support AGA domestic and international members and the gastroenterology community needs, be it patient care and those who provide the care, basic and clinical scientific discovery, education and training, advocacy, and ABIM recertification. I look forward to working with you and for you throughout the year.

Sincerely, Bishr Omary, MD, PhD, AGAF AGA Institute President

AGA probiotic guideline

ew AGA guideline finds that evidence to support use of probiotics to treat digestive diseases is greatly lacking, identifying only three clinical scenarios where probiotics may benefit patients.

After conducting a detailed review of available literature, AGA has released new clinical guidelines. This is the first clinical guideline to focus on probiotics across multiple GI diseases while also considering the effect of each single-strain or multistrain formulation of probiotics independently instead of grouping them all under the single umbrella of "probiotics."

Key guideline recommendations:

- For preterm (born before 37 weeks), low birthweight (<2,500 g) infants, specific probiotics can prevent mortality and necrotizing enterocolitis, reduce the number of days required to reach full feeds, and decrease the duration of hospitalization.
- Certain probiotics should be

considered for the prevention of *C. difficile* infection in adults and children who take antibiotics and for the management of pouchitis, a complication of ulcerative colitis that has been treated surgically.

- Probiotics do not appear to be beneficial for children in North America who have acute gastroenteritis

 they should not be given routinely to children who present to the emergency department because of diarrhea.
- There was insufficient evidence for AGA to recommend the use of probiotics to treat C. difficile infection, Crohn's disease, ulcerative colitis, or IBS. For these conditions, AGA suggests that patients consider stopping probiotics, as there are associated costs and not enough evidence to suggest lack of harm. Gastroenterologists should suggest the use of probiotics to their patients only if there is clear benefit and should recognize that the effects of probiotics are not species-specific, but strain- and combination-specific. ginews@gastro.org

The AGA Research Foundation funded 17 awards in 2020

The American Gastroenterological Association is excited to announce the 17 researchers selected to receive funding through the AGA Research Foundation Awards Program. The 2020 award year will provide \$2.2 million in research funding to support outstanding investigators working on projects that will enhance our understanding of gastroenterology and liver conditions and ultimately lead to better treatment options for patients with digestive disorders.

"The awardees this year have research projects that span the entire digestive tract. These projects have the potential to transform the field," said Robert S. Sandler, MD, MPH, AGAF, chair, AGA Research Foundation. "We are excited to continue the foundation's support of gifted early career researchers and look forward to seeing how their research evolves with this funding."

Of the 2020 class of awardees, half are women and 12% are from

racial or ethnic groups traditionally underrepresented in biomedical research. In line with the AGA Research Foundation's mission to support the next generation of researchers in digestive diseases, 71% of the 2020 awardees are early career investigators. Approximately one-third are performing clinical research.

The AGA Research Foundation Awards Program recruits, retains, and supports the most promising researchers in gastroenterology and hepatology. With funding from the foundation, recipients have protected time to take their research to the next level.

To view the full list of recipients go to gastro.org/2020awardees.

The AGA awards program is made possible thanks to generous donors and funders. Learn more about the AGA Research Foundation at http://foundation.gastro. org.

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Telemedicine update

What you need to know about payment parity, coding, advocacy, and more from our experts.

Payment parity

CMS's announcement of telehealth reimbursement payment parity is a huge win for our community. After weeks of active engagement with CMS, Congress, and the administration, CMS announced that it will reimburse audio-only E/M telehealth visits at the same rate as in-person rates. Thank you to all the members that engaged and took action on this issue. Your involvement was critical to our success.

How to code to maximize your reimbursement

Rules for coding for telemedicine have changed a lot since the beginning of the COVID-19 public health emergency (PHE). To ensure Medicare payment at rates equivalent to E/M codes 99212-99214, report modifier 95 and the place of service where the visit would have happened in person if not for the PHE.

Some commercial payers cover telephone E/M visits, but you'll need to check each patient's individual plan.

Here are some tips for telemedicine/virtual visit coding for Medicare patients:

Telehealth E/M (video visits) – Medicare requires a real-time audio and video connection to report E/M as telehealth. During the COVID-19 PHE, E/M level selection (99201-99205, 99211-99215) can be made based on medical decision-making or time. If selecting based on time, you may use either the 2020 or 2021 times in the E/M code descriptions. For Medicare, time is counted as the total spent on the day of the visit, not just face-to-face time. Commercial payors typically count only face-to-face time but check with each commercial patient's plan to be sure. Don't forget to report modifier 95 and the place of service where the visit would have happened in person if not for the PHE. If you had trouble with the connection and needed to switch to a telephone call, you can still report the visit as telehealth if over 50% of it was completed using the real-time audio/video platform or app.

Telephone E/M – Medicare now pays for telephone E/M codes 99441-99443 at the same rates as office/outpatient established patient E/M codes 99212-99214, but you must report modifier 95 and the place of service where the visit would have happened in person if not for the PHE. Medicare will also allow reporting of telephone E/M for new or established patients.

Online digital E/M – Medicare allows communication with patients via the practice's online patient platforms to be reported with codes 99421-99423. These codes are not considered telehealth services, so no special modifiers are required. They must be patient initiated. Communications can occur over a 7-day period via portal, fax, or phone, or a combination. Do not report online digital E/M codes if the online patient request is related to an E/M service within the previous 7 days or within the global period.

Virtual check-ins – Medicare created virtual check-in codes G2010 and G2012 in 2019. According to the CMS, they were created for "a brief communication technology-based service when the patient checks in with the practitioner via telephone or other telecommunications device to decide whether an office visit or other service is needed." The virtual visit codes can still be used this way during the COVID-19 PHE but remember that CMS also allows coverage for telephone E/M (99441-99443) which may be a more appropriate choice for telephone calls depending on the nature of the request and the patient's clinical issues.

Review AGA's telehealth coding and coverage guide for more details. To see FAQs on telemedicine from the AGA Community, check out GI COVID-19 Connection: Telemedicine for Today's GIs.

With telehealth serving as the main mechanism to deliver care to patients and a lifeline to private practices, we understand this is a priority for you and your colleagues. With the Alliance of Specialty Medicine, we continue to urge CMS to make the payment parity and eased telehealth waivers and regulations permanent beyond the public health emergency.

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CLINICAL CHALLENGES AND IMAGES

The diagnosis

Answer to "What is your diagnosis? on page 10: Fibroepithelial polyp of the hypopharynx Our patient underwent an upper endoscopy to evaluate symptoms of refractory gastroesophageal reflux disease and was found to have a large hiatal hernia. Upon careful endoscopic withdrawal, the polyp was briefly visualized as it was pulled back into the oropharynx. The patient was referred for flexible laryngoscopy that confirmed a polypoid mass involving



the right lateral piriform wall. She subsequently underwent direct laryngoscopy with harmonic scalpel-assisted excision of the lesion leading to resolution of her symptom of oropharyngeal dysphagia. The surgical specimen measured 3 \times 1.4 \times 0.4 cm. Pathology demonstrated benign overlying squamous mucosa with submucosa composed of bland spindle cells and fat, consistent with a benign fibroepithelial polyp (Figure C, original magnification \times 100; stain: hematoxylin and eosin).

Fibroepithelial polyps are rare benign lesions of the hypopharynx and proximal esophagus that can lead to oropharyngeal dysphagia.¹ Larger hypopharyngeal polyps have been associated with aspiration and airway compromise.¹ Owing to their proximal location, these lesions are more readily identified under flexible laryngoscopy, but can also be observed with esophagogastroduodenoscopy. Cross-sectional imaging of the neck can be considered for patients with oropharyngeal dysphagia and a normal video-swallow study. Although the underlying pathogenesis remains unclear, inflammation or infection may play a role, especially in smokers.² The rate of recurrence after resection is low.¹

Further evaluation for her symptomatic hiatal hernia was performed and the patient ultimately underwent a laparoscopic Nissen fundoplication with wedge gastroplasty, leading to improvement in her symptoms of gastroesophageal reflux disease. This case illustrates that, although esophagogastroduodenoscopy is not considered the first step in the evaluation of patients with oropharyngeal dysphagia, a careful examination can sometimes reveal the diagnosis.

References

1. Caceres M et al. Large pedunculated polyps originating in the esophagus and hypopharynx. Ann Thorac Surg. 2006;81:393-6.

2. Maskey AP et al. Endobronchial fibroepithelial polyp. J Bronchology Interv Pulmonol. 2012;19:313-4.

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GI ONCOLOGY

Physical activity also critical

Cancer from page 1

ing nonprofit health organizations, including the ACS and the World Cancer Research Fund/American Institute for Cancer Research, have released cancer prevention guidelines and recommendations that focus on managing weight, diet, physical activity, and alcohol consumption.

In 2012, the ACS issued guidelines on diet and physical activity, and their current guideline is largely based on the WCRF/AICR systematic reviews and Continuous Update Project reports, which were last updated in 2018.

Emphasis on three areas

The differences between the old guidelines and the update do not differ dramatically, but Dr. Makaroff highlighted a few areas that have increased emphasis.

Time spent being physically active is critical. The recommendation has changed to encourage adults to engage in 150-300 minutes (2.5-5 hours) of moderate-intensity physical activity, or 75-150 minutes (1.25-2.5 hours) of vigorous-intensity physical activity, or an equivalent combination, per week. Achieving or exceeding the upper limit of 300 minutes is optimal.

"That is more than what we have recommended in the past, along with the continued message that children and adolescents engage in at least 1 hour of moderate- or vigorous-intensity activity each day," Dr. Makaroff said in an interview.

The ACS has also increased emphasis on reducing the consumption of processed and red meat. "This is part of a healthy eating pattern and making sure that people are eating food that is high in nutrients that help achieve and maintain a healthy body weight," she said.

A healthy diet should include a variety of dark green, red, and orange vegetables; fiber-rich legumes; and fruits with a variety of colors and whole grains, according to the guidelines. Sugar-sweetened beverages, highly processed foods, and refined grain products should be limited or avoided.

The revised dietary recommendations reflect a shift from a "reductionist or nutrient-centric" approach to one that is more "holistic" and that focuses on dietary patterns. In contrast to a focus on individual nutrients and bioactive compounds, the new approach is more consistent with what and how people actually eat, ACS points out.

The third area that Dr. Makaroff highlighted is alcohol, where the recommendation is to avoid or limit consumption. "The current update says not to drink alcohol, which is in line with the scientific evidence, but for those people who choose to drink alcohol, to limit it to one drink per day for women and two drinks per day for men."

Thus, the change here is that the previous guideline recommended only limiting alcohol consumption, while the update suggests that, optimally, it should be avoided completely.

The ACS has also called for community involvement to help implement these goals: "Public, private, and community organizations should work collaboratively at national, state, and local levels to develop, advocate for, and implement policy and environmental changes that increase access to affordable, nutritious foods; provide safe, enjoyable, and accessible opportunities for physical activity; and limit alcohol for all individuals."

No smoking guns

Commenting on the guidelines, Steven K. Clinton, MD, PhD, associate director of the Center for Advanced Functional Foods Research and Entrepreneurship at the Ohio State University, Columbus, explained that he didn't view the change in alcohol as that much of an evolution. "It's been 8 years since they revised their overall guidelines, and during that time frame, there has been an enormous growth in the evidence that has been used by many organizations," he said.

Dr. Clinton noted that the guidelines are consistent with the whole body of current scientific literature. "It's a pattern, and what dietitians and nutritionists are telling people is that you need to orchestrate a healthy lifestyle and diet, with a diet that has a foundation of fruits, vegetables, whole grains, and modest intake of refined grains and meat. You are orchestrating an entire pattern to get the maximum benefit."

Dr. Makaroff is an employee of the ACS. Dr. Clinton has disclosed no relevant financial relationships.

A version of this article originally appeared on Medscape.com.



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- Considerations for colonic motility
- An FDA-approved treatment option for adults with CIC

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AGA CPU: Maintain IBD remission during pandemic

BY RICHARD MARK KIRKNER MDedge News

nflammatory bowel disease (IBD) does not seem to make patients any more likely to contract SARS-COV-2 or develop COVID-19, but a rapid review commissioned by the American Gastroenterological Association acknowledges that determination is based on limited evidence and IBD patients should nonetheless maintain remission to reduce their risk of relapse or hospitalization during the COVID-19 pandemic.

The AGA has published a clinical practice update based on that rapid review online in Gastroenterology (2020. doi: 10.1053/j.gastro.2020.04.012).

Because of the widespread use of immunosuppressive or immune-modifying drugs, "It is understandable why patients with Crohn's disease and ulcerative colitis have specific concerns and potential for increased risk of infection with SARS-CoV-2," wrote David T. Rubin, MD, AGAF, of the University of Chicago and coauthors.

In accordance with the IOIBD (International Organization for the Study of Inflammatory Bowel Disease) consensus, the update noted that IBD patients should continue going to infusion centers for therapies, provided that the centers use a COVID-19 screening protocol.

Patients with IBD who contract COVID-19 seem more likely to be hospitalized for one or the other disease, but that's based on data from the international SECURE-IBD registry that had 164 patients as of the writing of the update. The update provides guidance for three scenarios for IBD patients during the pandemic:

- Patients not infected with SARS-CoV-2 should maintain their IBD therapies to sustain remission and avoid relapses. "Aside from the obvious negative consequences of a relapse, relapsing IBD will strain available medical resources, may require steroid therapy or necessitate hospitalization, outcomes that are all much worse than the known risks of existing IBD therapies," Dr. Rubin and colleagues noted.
- Patients who are infected but have no symptoms of COVID-19 should have their dosing of prednisone adjusted to less than 20 mg/day or switched to budesonide; suspend thiopurines, methotrexate, and tofacitinib; and delay dosing of monoclonal antibodies (anti–tumor necrosis factor [anti-TNF] drugs, ustekinumab, or vedolizumab) for 2 weeks while their symptoms of

COVID-19 are monitored. "Restarting therapy after 2 weeks if the patient has not developed manifestations of COVID-19 is reasonable," wrote Dr. Rubin and colleagues. "Emerging serial testing should indicate antibody status."

In the patient with confirmed COVID-19, adjustment of IBD therapy "is appropriate, based on the understanding of the immune activity of the therapy and whether that therapy may worsen outcomes with COVID-19," the update stated. Therapy adjustment should focus on reducing immune suppression during the active viral infection. Some studies are evaluating anticytokine-based therapies as COVID-19 treatments, so continued anti-TNF therapies might prevent acute respiratory distress syndrome and multiorgan failure. "However, ... guidance is currently based on deciding whether to hold or to

continue specific IBD therapies." During the acute stage of COVID-19, thiopurines, methotrexate, and tofacitinib should be discontinued, and anti-TNF drugs and ustekinumab should be stopped during viral illness. Holding vedolizumab during viral illness is also appropriate, according to the update, although the IOIBD group was uncertain if doing so was necessary.

If the IBD patient has digestive symptoms with COVID-19, ongoing supportive care of the COVID-19 is "reasonable," but investigating the causes of the digestive symptoms "is critically important." That should include ruling out enteric infections and confirming active inflammation with nonendoscopic testing. Endoscopy should be relegated to only urgent and emergent cases.

In hospitalized patients with severe COVID-19 and poor prognoses, "IBD therapy will likely take a back seat," the update stated, although COVID-19 therapies should take the concomitant IBD into account. In patients with milder cases of COVID-19, IBD management should focus on acute manifestations, but intravenous steroid therapy shouldn't exceed 3 days. The update urged providers to submit cases of IBD and confirmed COVID-19 to the SECURE-IBD registry at COVIDIBD.org.

Dr. Rubin and coauthors disclosed financial relationships with AbbVie, Boehringer Ingelheim, Gilead Sciences, Takeda, and many other pharmaceutical companies.

ginews@gastro.org

SOURCE: Rubin DT et al. Gastroenterology. 2020. doi: 10.1053/j.gastro.2020.04.012.

Sulfasalazine risky, too

Steroids from page 1

Hill, and Ryan C. Ungaro, MD, of Icahn School of Medicine at Mount Sinai, New York, and colleagues.

In contrast, tumor necrosis factor (TNF) blockers were not an independent risk factor for severe COVID-19.

"As TNF antagonists are the most commonly prescribed biologic therapy for patients with IBD, these initial findings should be reassuring to the large number of patients receiving TNF antagonist therapy and support their continued use during this current pandemic," the investigators wrote in Gastroenterology (2020 May 18. doi: 10.1053/j.gastro.2020.05.032).

These conclusions were drawn from the Surveillance Epidemiology of Coronavirus Under Research Exclusion for Inflammatory Bowel Disease (SECURE-IBD) database, a large registry actively collecting data from clinicians around the world.

In the present analysis, which involved 525 patients from 33 countries, the investigators searched for independent risk factors for severe COVID-19. Various factors were tested through multivariable regression, including age, comorbidities, usage of specific medications, and more.

The primary outcome was defined by a composite of hospitalization, ventilator use, or death, while secondary outcomes included a composite of hospitalization or death, as well as death alone.

The analysis revealed that patients receiving corticosteroids had an adjusted odds ratio of 6.87 (95% confidence interval, 2.30-20.51) for severe

COVID-19, with increased

risks also detected for both

not significantly associated

with the primary outcome;

in fact, a possible protective

effect was detected for hospi-

talization or death (aOR, 0.60;

The investigators noted that

95% CI, 0.38-0.96).

secondary outcomes. In con-

trast, TNF antagonist use was



Dr. Rubin

the above findings aligned with extensive literature concerning infectious complications with corticosteroid use and "more recent commentary" surrounding TNF antagonists.

But the threefold increased risk of severe COVID-19 associated with use of sulfasalazine or 5-ASAs (aOR, 3.14; 95% CI, 1.28-7.71) was a "surprising" finding, the investigators noted.

"In a direct comparison, we observed that 5-ASA/sulfasalazine-treated patients fared worse than those treated with TNF inhibitors," the investigators wrote. "Although we cannot ex-

AGA Resource

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clude unmeasured confounding, further exploration of biological mechanisms is warranted."

David T. Rubin, MD, AGAF, of the University of Chicago agreed that the finding deserves further investigation, particularly since sulfasalazine and 5-ASAs represent the second most commonly prescribed medication class for IBD.

"The risk with 5-ASAs is of interest but not well explained by what we know about the safety or the mechanism of these therapies," Dr. Rubin said. "Clearly, more work is needed."

The risks associated with corticosteroids were particularly concerning, Dr. Rubin said, because 10%-20% of patients with IBD may be taking corticosteroids at any given time.

"Steroids are still the number one prescribed therapy for Crohn's and colitis," he said.

Still, Dr. Rubin advised against abrupt changes to drug regimens, especially if they are effective-*Continued on following page*

Endoscopic myotomy for achalasia

Endoscopic myotomy is ready for prime time

BY MOUEN A. KHASHAB, MD

eroral endoscopic myotomy (POEM) has deservingly taken a prime time spot in the management of patients with achalasia. It is an efficient, efficacious, and safe treatment modality that results in rapid resolution of achalasia symptoms in the majority of patients. Research should focus on technical modifications (e.g., short gastric myotomy; addition of endoscopic fundoplication) that reduce the incidence of postprocedural



Dr. Khashab

division of gastroenterology and hepatology, Johns Hopkins Hospital, Baltimore. He is a consultant for BSCI, Olympus, and Medtronic.

gastroesopha-

geal reflux dis-

ease (GERD).

Dr. Khashab is

medicine, direc-

tic endoscopy,

an associate

professor of

Dear colleagues and friends,

Heller myotomy is still the gold standard

BY ROBERT M. SIWIEC, MD

yotomy of the lower esophageal sphincter (LES) decreases pressure across the esophagogastric junction and eliminates dysphagia in patients with achalasia. Unfortunately, myotomy of the LES disrupts the main antireflux

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barrier increasing the risk of GERD. Unlike laparoscopic Heller myotomy (LHM), no concomitant fundopli-

cation is performed during POEM resulting in significantly higher rates of pathologic reflux and associated complications including Barrett's esophagus and even adenocarcinoma.



Dr. Siwiec

Unfortunately, guidelines regarding prevention, effective treatment, and appropriate surveillance of post-POEM GERD are lacking. Although POEM has been shown to have a distinct advantage in patients with type III achalasia by nature of the longer myotomy not achievable by laparoscopic means, LHM with fundoplication to this day remains a tried-and-tested treatment option for patients with non-type III achalasia.

Dr. Siwiec is assistant professor of clinical medicine, division of gastroenterology and hepatology, GI Motility and Neurogastroenterology Unit, Indiana University School of Medicine, Indianapolis. He has no conflicts ..



"Patients should stay on their existing therapies and stay in remission," Dr. Rubin said. "If you stop your therapies ... you are more likely to relapse. When you relapse, you're more likely to need steroids as a rescue therapy ... or end up in the hospital, and those are not places we want you to be."

He noted that the SECURE-IBD registry, which he has contributed to, represents "an extraordinary effort" from around the world.

"[This is] an unprecedented collaboration across a scale and timeframe that has really never been seen before in our field, and I would hazard a guess that it's probably never been seen in most other fields right now," he said.

Clinicians seeking more information about managing patients with IBD during the COVID-19 pandemic can find guidance in the recent AGA practice update, of which Dr. Rubin was the lead author. Clinicians who would like to contribute to the SECURE-IBD registry may do so at covidibd.org. The registry now includes more than 1,000 patients.

The study was funded by Clinical and Translational Science Award grants through Dr. Ungaro. The investigators disclosed relationships with Takeda, Janssen, Pfizer, and others. Dr. Rubin disclosed relationships with Gilead, Eli Lilly, Shire, and others.

ginews@gastro.org

SOURCE: Brenner EJ et al. Gastroenterology. 2020 May 18. doi: 10.1053/j.gastro.2020.05.032.

n this edition of Perspectives, Dr. Mouen Khashab and Dr. Robert Siwiec tackle an exciting and constantly evolving topic, which is the optimal approach to myotomy for patients with achalasia. Dr. Khashab makes the case for endoscopic myotomy, while Dr. Siwiec argues that surgical myotomy remains the gold standard. I hope that you will find this debate as useful and thought-provoking as I

did. As always, I welcome your comments and sug-

gestions for future topics at ginews@gastro.org.

Dr. Kahi

Charles J. Kahi, MD, MS, AGAF, professor of Medicine, Indiana University School of Medicine, Indianapolis. He is also an Associate Editor for GI & Hepatology News.

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> ENDOSCOPY

Discern time-sensitivity of procedure

N95 masks from page 1

guideline panel met in March.

The document includes seven recommendations for use of personal protective equipment by physicians and nurses performing GI procedures. The recommendations and the level of evidence supporting them fall under four categories: Masks, comprising four recommendations: use of N95 masks for upper and lower GI procedures regardless of a patient's COVID-19 status; no use of only surgical masks in confirmed COVID-19 patients or suspected cases; and use of reused N95 masks when fresh ones aren't available instead of using a surgical mask only (very low to moderate level of evidence depending on the recommendation).

2 Double-gloving when performing any GI procedure regardless of the patient's COVID-19 status (moderate quality evidence).
 3 When available, a negative-pressure room for any COVID-19 patient or suspect rather than a regular endoscopy room (very low certainty of evidence).

4 Standard cleaning, endoscopic disinfection, and reprocessing protocols regardless of a patient's COVID-19 status (good practice statement).

For decontamination, the panel

noted that commonly used biocidal agents, such as hydrogen peroxide, alcohols, sodium hypochlorite, or benzalkonium chloride have proved effective for decontaminating of coronavirus.

For implementing the PPE recommendations, the panel stated that personnel still need to practice don and doff standard protocols, and that N95 masks should be fitted for each individual.

Other steps include banning personal belongings in the procedure area; minimizing the number of personnel in the room; avoiding change of personnel and keeping nonprocedural personnel out during the procedure; considering use of nursing teams that follow the patient through preprocedure, procedure, and recovery, and considering having endoscopy teams remain together during the day to minimize exposure.

The triage recommendations stated that "trained medical personnel" should review all procedures and categorize them as time-sensitive or not time-sensitive, based on a framework the recommendation includes. In "an open-access endoscopy system" when there isn't enough information to determine timing for the procedure, the recommendation provides a three-step approach: a phone consult with the referring physician, a telehealth visit with the patient, or a multidisciplinary team approach or virtual disease/tumor board.

"The proposed framework of separating procedures into time-sensitive and non-time-sensitive cases may be useful in determining which

The recommendations offer guidelines for triaging patients for endoscopy and timing of nonurgent procedures, and evaluate the latest evidence in the incidence of GI and liver manifestations of COVID-19.

procedures if delayed may negatively impact on patient-important outcomes," wrote Shahnaz Sultan, MD, AGAF, of the University of Minnesota, Minneapolis, and colleagues. The panel noted decision-making should focus on "patient-important outcomes."

For nonurgent procedures, the panel arrived at a consensus that 8 weeks was an appropriate window for reassessment of deferred procedures, depending on the availability of resources and if the time-sensitivity of the procedure changes.

The panel also attempted to determine the likelihood of GI and liver manifestations of COVID-19 by evaluating published cohort studies. They found that 2%-13.8% of patients had diarrhea, 1%-10.1% had nausea or vomiting, and one study reported 2% had abdominal pain (Am J Gastroenterol. 2020 May;115[5]766-73). What's more, some studies have shown stool samples positive for SARS-CoV-2 RNA even after respiratory samples were negative.

The evidence on liver manifestations isn't as robust, but one study reported that 20%-30% of patients had liver injury upon diagnosis of COVID-19 (Gastroenterology. 2020;158:1518-9), and that severe hepatitis has been reported but liver failure seems rare (Lancet. 2020 Feb 15;395[10223]:507-13). "The pattern of liver injury appears to be predominantly hepatocellular, and the etiology remains uncertain but may represent a secondary effect of the systemic inflammatory response observed with COVID-19 disease, although direct viral infection and drug-induced liver injury cannot be excluded," Dr. Sultan and colleagues noted.

There were no relevant author conflicts of interest. The American Gastroenterological Association (AGA) Institute funded the study.

SOURCE: Sultan S et al. Gastroenterology. 2020. doi: 10.1053/j.gastro.2020.03.072.

> COVID-19 ROUNDUP

Defending docs against retaliation, mortality high in diabetic patients

BY LUCAS FRANKI MDedge News

New group seeks to defend health professionals facing retaliation

Beacon, a new organization founded by Sejal Hathi, MD; John Paul Schnapper-Casteras, JD; and Sheel Tyle, JD, is undertaking their first project, which seeks to protect the legal rights of medical professionals who have spoken out on personal protective equipment shortages and other coronavirus-related matters of public safety.

"When health care workers share knowledge, correct problems – and in some cases, blow the whistle – it affirmatively benefits medical science, disease control, and the public interest. We have seen in other countries the disastrous consequences that can stem from silencing medical professionals who try to speak out," Mr. Schnapper-Casteras said.

Beacon has issued a strongly worded letter on behalf of health care workers outlining the legal obligations of hospitals to ensure workplace safety, as well as reminding hospitals that there are federal regulations protecting employees who exercise their workplace rights. They are also working with health care workers to remind them of their workplace rights and legal options.

Mortality high for hospitalized patients with diabetes, COVID-19

More than 10% of patients with diabetes who are hospitalized for COVID-19 die within a week, with about a third requiring mechanical ventilation, according to a study published in Diabetologia (2020 May 29. doi: 10.1007/s00125-020-05180-x).

Body mass index was independently associated with death, with diabetes-related complications and older age also increasing the risk. Hemoglobin A1c and use of renin-angiotensin-aldosterone system blockers and dipeptidyl peptidase–4 inhibitors were not associated with increased mortality.

In addition, "elderly populations with longterm diabetes with advanced diabetes-related complications and/or treated obstructive sleep apnea were particularly at risk of early death and might require specific management to avoid infection," the investigators wrote.

Mass protests could lead to COVID-19 outbreaks

Health officials have expressed concern about the potential for a spike in COVID-19 cases as mass protests continue in cities across the United States.

In Minnesota, for example, COVID-19 cases and hospitalizations had been increasing in days even before the protests started, according to former FDA commissioner Scott Gottlieb.

While the protests were generally peaceful with good adherence to social distancing, some evolved into more violent gatherings where social distancing was impossible. People who have the virus but don't show symptoms may infect others without knowing it, as chanting, singing, and shouting may spread the virus through respiratory droplets.

"If you were out protesting last night, you probably need to go get a COVID test this week," Atlanta Mayor Keisha Lance Bottoms said.

Frontline associate editor Lucas Franki compiled this column from reports first published on MDedge.com and Medscape.com.

WHO clarifies comments on asymptomatic SARS-CoV-2

BY JEFF CRAVEN MDedge News

World Health Organization official is walking back her comments characterizing the spread of SARS-CoV-2 by asymptomatic individuals as "rare."

Maria Van Kerkhove, PhD, WHO's COVID-19 technical lead and an infectious disease epidemiologist, caused a stir June 8 when she said that countries are reporting that many of their asymptomatic cases develop into cases of mild disease. For patients with truly asymptomatic disease, countries are "not finding secondary transmission onward. It's very rare," she said.

Suppressing symptomatic cases, on the other hand, would result in a "drastic reduction" in transmission, she noted. "But from the data we have, it still seems to be rare that an asymptomatic person actually transmits onward to a secondary individual," she said.

But on June 9 – following a day of confusion and criticism – Dr. Van Kerkhove sought to clarify her comments on asymptomatic transmission during a live social media Q&A. She noted that, while "the majority of transmission that we know about" is through individuals with symptoms, "there are a subset of people who don't develop symptoms, and to truly understand how many people don't have symptoms – we don't actually have that answer yet."

Between 6% and 41% of individuals may be asymptomatic based on estimates, she acknowledged.

"What we need to better understand is how many of the people in the population don't have symptoms, and separately, how many of those individuals go on to transmit to others," she said.

Dr. Van Kerkhove said her initial comments were made in response to a question raised at the press conference. "I wasn't stating a policy of WHO or anything like that," she said. "I was just trying to articulate what we know."

The phrase "very rare" referred to a subset of studies and reports WHO had received from its member states following asymptomatic individuals with COVID-19. "I was referring to some detailed investigations, cluster investigations, case contact tracing, where we had reports from member states saying that, when we follow asymptomatic cases, it's very rare – and I used the phrase very rare – that we found a secondary transmission," she said.

Dr. Van Kerkhove's initial comments drew criticism from medical and public health professionals, who said the statement was "confusing" and communicated poorly.

Eric J. Topol, MD, tweeted that WHO had "engendered considerable confusion" with the comments about asymptomatic individuals rarely transmitting SARS-CoV-2. Dr. Topol, the author of a recent analysis published in Annals of Internal Medicine that suggested as many as 40%-45% of COVID-19 cases may be asymptomatic, said that it was not possible to determine whether asymptomatic individuals in the cohorts he studied were capable of spread like presymptomatic individuals. "We only know the viral loads are similar from multiple reports. And we do know some spread occurs from [asymptomatic] people," he said.

Anthony S. Fauci, MD, director of the National Institute of Allergy and Infectious Diseases, also weighed in on the controversial WHO comments, telling Good Morning America on June 10 that Dr. Van Kerkhove's initial statement that asymptomatic SARS-CoV-2 transmission is a rare event is "not correct."

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> PRACTICE MANAGEMENT TOOLBOX

Private practice to private equity-backed MSO – Perspectives from the United Digestive team: Part 2

BY NEAL PATEL, MD, AND MARC SONENSHINE, MD, MBA

Author's note: In December 2018, Atlanta Gastroenterology Associates partnered with Frazier Healthcare Partners to form the practice management company United Digestive

(UD). Since that time, colleagues across the country have evaluated their own private equity prospects and partnerships, as well as monitored the progress of our transition.

So how are things going? Enjoy part two of this two-part article where we reached out to several team members

from all levels within the organization and asked them to share their personal experiences – both highlights and challenges – during UD's first year.

Did you miss Part 1? Don't worry, you can read Part 1 here (https:// www.mdedge.com/gihepnews/ practice-management-toolbox).





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There are several private equitybacked GI practice management groups across the country. Why did you and your colleagues decide to partner with UD last year, and, how is the relationship going to date? Mark Murphy, MD, UD Physician Executive Committee Member Center for Digestive and Liver Health in Savannah, Ga.

 "We previously investigated other partnerships but felt they really did not bring enough value to make our group stronger or more viable. United Digestive was different. The idea of partnering with like-minded gastroenterologists to become a larger, single-specialty entity, with contract negotiation leverage and economies of scale was appealing and would not be possible as a 10-person group. Further, the partnership represented an opportunity to eliminate debt, minimize future risk to younger partners, and yet also embrace an ability to add new services and physicians.

"There were expected hiccups in the beginning: specifically IT and HR issues, which were remedied appropriately and timely. One month after the partnership was completed, reports started coming out of China about a new viral illness - an illness that telescoped our perspective on the consequences of our decision into a timeline of months rather than years.

"UD's response to the COVID-19 epidemic has been phenomenal. The organization made the tough, but proper clinical calls that limited risks to patients and staff. They came up with a game plan to salvage fiscal viability - rolling out telemedicine in a matter of days and establishing the manner in which patients with high acuity could still be seen and cared for expediently.

"As a solo GI practice, we would have struggled mightily to survive and might have gone bankrupt.

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Had we been part of a larger non-GI entity (a hospital or multispecialty group), we might have been pressured to engage in unsafe or unethical practices and not consistent with national societal recommendations. Instead, we found ourselves having active discussions with our GI colleagues about the right path forward."

How do you feel UD has helped improve the quality of patient care and positively impacted patient satisfaction?

- Aja McCutchen, MD
- "Prior to UD, we worked diligently to improve our centralized patient service center, phone trees, and optimize the time and communication between patients, providers, and our staff. We now have tools which help identify and track gaps in communication on all levels. We have been able to improve our MA work flow, shorten wait times, and improve the direct dialogue between our practice and our patients. We have also been able to enhance our ancillary service offerings and expand programs that directly benefit our patients."

Kimberly Orleck, PA-C

 "I think our quality of care has always been top notch and that thankfully has not been altered. UD has concentrated on workflow optimization, enhanced training to our frontline teams, and improved scheduled processes to decrease patient wait time. UD is also paying closer attention to patient ratings, reviews, and calculating net promotor scores."

Have there been any initiatives in the first year which improved the management of the organization? Elizabeth Escalante, Senior Regional

Director of Operations, UD

• "Implementation of a business analytics tool was huge this year. It greatly improved visibility into the information we need to have at our fingertips in order to make data-driven decisions for our business. Drilling this down to the frontline manager has increased our understanding of what it truly takes to run a successful practice, and in turn, increased stakeholder buy-in."

Lakeeta White, Clinical Office Team Lead, and Alexis Sweeney, Medical Assistant

• "The formation of our MA Advisory Committee has been instrumental in helping standardize best practices across the organization. It is comprised of medical assistants across our geographic footprint, and they provide feedback to the management team regarding process improvements, areas for continued training, and more."

Though many positives may arise out

of change, so can some challenges. Have there been any unforeseen hurdles you experience as a result of the new partnership with PE? *Elizabeth Escalante*

• "Overall, I believe the changes to the structure of the practice and reorganization of leadership has been positive. As with any organization, one area of improvement is in communication."

Dr. Patel and Dr. Sonenshine are with Atlanta Gastroenterology Associates, which is part of United Digestive. They have no conflicts.

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